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Award Number: W81XWH-10-2-0133

TITLE: Treatment of Early Post-op Wound Infection after Internal Fixation

PRINCIPAL INVESTIGATOR: William Obremskey, M.D.

CONTRACTING ORGANIZATION: Vanderbilt University Medical Center
Nashville, TN 37203

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REPORT DATE: October 2010

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TYPE OF REPORT: Annual

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PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE						Form Approved OMB No. 0704-0188	
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1. REPORT DATE October 201G			2. REPORT TYPE Annual			3. DATES COVERED 15 September 201F – 14 September 201G	
4. TITLE AND SUBTITLE Treatment of Early Post-op Wound Infection after Internal Fixation						5a. CONTRACT NUMBER	
						5b. GRANT NUMBER W81XWH-10-2-0133	
						5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) William Obremskey E-Mail: william.obremskey@vanderbilt.edu						5d. PROJECT NUMBER	
						5e. TASK NUMBER	
						5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Vanderbilt University Medical Center Nashville, TN 37203						8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012						10. SPONSOR/MONITOR'S ACRONYM(S)	
						11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited							
13. SUPPLEMENTARY NOTES							
14. ABSTRACT Ú[•q] ^!æç^Á ¯&ç} Á Á } ^ Á - @ Á [• Á ! ç æ ^) ó æ á & ç æ ^ * ä * Å {] æ æ } • Á æ á Á Á ! c q] æ á á Á ~ ! * ^ [] • Á æ á Á æ æ } • Á á Á [c b - @ Á á æ æ Á æ á Á æ æ Á [] ~ æ æ } • É V @ Á [~ } á • Á æ Á Å [] æ ä æ á Á Á Å [] á á Á æ á @ Á Á Á Á Á b i ' É æ í ä * Á @ Å ~ ! Á Á [- @ : æ } É Á Á [c b - @ ¯ & ç } Á Á æ æ • Á æ [• • æ æ æ Á á æ æ Á ~ ! * æ æ ç c í ç ^) ç } É æ æ æ æ Á Á @ Á ^ ç æ * Á Á ! c q] æ á á Á d æ { æ æ @ ! ^ Á ~ ç ^ Á æ æ } • Á æ á Á @ Á ! ^ ç ^) ç } Á æ á Á ^ æ [^) o Á Á @ • Á Á ¯ & ç } • Á ^ ! ^ Å [] æ æ á É Á ^ Á æ Á ç æ æ æ * Á @ Á ^ ¯ & ç ^) • • • Á Á [Á • Á Á æ ç æ ç Á Á Á ~] ^ • • ä } Á æ á Á ! æ æ æ æ } Á Á æ Á [• o Á] Á [~ } á Á ¯ & ç } • Á Á æ ç ! ^ Á æ æ ä á á Á á @ Á] æ • É V ^ Á æ Á æ Á æ Á] ç æ Á [Á É Ú É Ç { ^ Á ^ á æ Á U ^ • æ & ç æ á Á æ á Á [{ { æ á c Á W U C E Ü T Ö D R ~ { æ Á U ^ • æ & ç Á U [c & ç } Á ~ æ Á P Ü Ü U D æ á Á æ á á á æ Á æ Á Á Á Á á Á á Á * ä Á } ; [^) ö Á Á [ç ^ á ! Á G F G S [æ á Á æ Á] ç æ Á W U C E Ü T Ö P Ü Ü U Á æ á Á Ö V Ü Ö Á] ç æ Á æ æ æ á Á Á ! Á Á æ • Á æ á Á Á @ ! Á æ • Á Á æ • Á æ Á æ æ æ * Á W U C E Ü T Ö P Ü Ü U Á æ] ç æ Á Ç æ Á Á Á Á Á • ç Á } c ! • Á æ Á Á } ä * Á Á á Á Á ~ o c á Á Á Á Á Á Á Á á Á c ! ^ • c á Á æ æ Á Á } c ! • É							
15. SUBJECT TERMS PO, IV, Antibiotics, plate, fixation, infection							
16. SECURITY CLASSIFICATION OF:				17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON	
a. REPORT	b. ABSTRACT	c. THIS PAGE	USAMRMC				
U	U	U	UU	5	19b. TELEPHONE NUMBER (include area code)		

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Final Report: “Treatment of Early Post-Op Wound Infection after Internal Fixation”, 2011-2012

Introduction:

Bone fracture is common in modern warfare with fractures being fixed via internal fixation of plates and screws to hold the fracture stable while the bone heals. Approximately 10%-40% of severe fractures fixed with internal fixation plates, however, develop a deep wound infection before the bone is completely healed. Thus, the overall goals of this study are to (1) compare the efficacy of antibiotic treatment (oral or intravenous for 6 weeks) in patients treated for wound infection after plate internal fixation of a fracture prior to bony union and (2) build and validate a risk prediction model for failure of treatment of early postoperative wound infections after plate fixation of fractures.

Body:

During the current reporting period, the Principal Investigator (PI) focused on administrative tasks essential to the initiation of the study. Here, the PI reports that a Data Safety Monitoring Board with a monitoring plan has been established, case report forms have been completed, and study brochures have been prepared. We also have attained provided training and distributed “Glow Caps” to provide further input on compliance with PO medication. Further, PIs have been identified for the study at each Major Extremity Trauma Research Consortium site. Local IRB approval, USAMRMC HRPO and METRC approval is attained for 2 sites and 3 other “test” sites are awaiting USAMRMC HRPO approval. These 5 test sites will identify issues with recruitment and administration of medication and monitoring prior to roll out at all centers.

Task 1	Months 1-6	completed
Task 2	Months 2-6	completed
Task 3	Months 7-30	Roll out of enrollment - initiated
Task 4	Months 7-42	Enrollment ongoing
Task 5	Months 43-48	Not yet initiated

PROBLEM AREAS:

- Complex study design required longer than usual review by local IRBs
- Slow process of approval by USAMRMC HRPO.
- Assessing compliance

NEXT STEPS:

- Enroll patients in test sites to assess challenges
- Roll out enrollment to other Core and Satellite centers.

- Work with sites to maximize enrollment of these rare patients
- Consider expansion of inclusion criteria to improve enrollment

Some institutions are working on mechanism for providing PO medication for uninsured patients.

Key Research Accomplishments:

- Developed compliance assessment mechanism for PO pills
- IRB, USAMRMC HRPO, and CC approval for 3 test sites with 2 pending
- CRFs and Database developed
- Distributed electronic data system live and ready to randomize patients at multiple sites

Reportable Outcomes: Pending

Conclusion: To date, we have finalized our protocol, established a DSMD with a monitoring plan and completed our CRF's. We have local IRB approval at the primary site (Vanderbilt) and USAMRMC HRPO. We have prepared study brochures in English and Spanish and implemented training processes for "glowcap" use and dissemination. We have trained personnel at each site and plan to begin screening and enrollment on November 1, 2012.

References:

None

Appendices:

None